

FORM PCT/390 (Modified)
(REV 10-95)

U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE

ATTORNEY'S DOCKET NUMBER

**TRANSMITTAL LETTER TO THE UNITED STATES
DESIGNATED/ELECTED OFFICE (DO/EO/US)
CONCERNING A FILING UNDER 35 U.S.C. 371**

1565

U.S. APPLICATION NO. (IF KNOWN, SEE 37 CFR

09/806639

INTERNATIONAL APPLICATION NO.
PCT/EP 99/07254

INTERNATIONAL FILING DATE
SEPTEMBER 30, 1999

PRIORITY DATE CLAIMED
OCTOBER 2, 1998

TITLE OF INVENTION

**USE OF TESTOSTERONE ESTERS AND/OR TESTOSTERONE FOR PRODUCING BUCCALLY APPLICABLE
BIO-ADHESIVE SYSTEMS WITH TIME-RELEASED ACTIVE INGREDIENTS**

APPLICANT(S) FOR DO/EO/US

**Dorie HUEBLER, Guenter KAUFMANN, Michael OETTEL, Holger ZIMMERMANN, Michael DITTGEN, Sabine
FRICKE, Manfred BOESE, Ralf LADWIG, Sven CLAUSSEN, Carsten TIMPE**

Applicant herewith submits to the United States Designated/Elected Office (DO/EO/US) the following items and other information:

1. ☒ This is a **FIRST** submission of items concerning a filing under 35 U.S.C. 371.
2. ☐ This is a **SECOND** or **SUBSEQUENT** submission of items concerning a filing under 35 U.S.C. 371.
3. ☐ This is an express request to begin national examination procedures (35 U.S.C. 371(f)) at any time rather than delay examination until the expiration of the applicable time limit set in 35 U.S.C. 371(b) and PCT Articles 22 and 39(1).
4. ☒ A proper Demand for International Preliminary Examination was made by the 19th month from the earliest claimed priority date.
5. ☒ A copy of the International Application as filed (35 U.S.C. 371 (c) (2))
 - a. ☐ is transmitted herewith (required only if not transmitted by the International Bureau).
 - b. ☒ has been transmitted by the International Bureau.
 - c. ☐ is not required, as the application was filed in the United States Receiving Office (RO/US).
6. ☒ A translation of the International Application into English (35 U.S.C. 371(c)(2)).
7. ☐ A copy of the International Search Report (PCT/ISA/210).
8. ☐ Amendments to the claims of the International Application under PCT Article 19 (35 U.S.C. 371 (c)(3))
 - a. ☐ are transmitted herewith (required only if not transmitted by the International Bureau).
 - b. ☐ have been transmitted by the International Bureau.
 - c. ☐ have not been made; however, the time limit for making such amendments has NOT expired.
 - d. ☐ have not been made and will not be made.
9. ☐ A translation of the amendments to the claims under PCT Article 19 (35 U.S.C. 371(c)(3)).
10. ☒ An oath or declaration of the inventor(s) (35 U.S.C. 371 (c)(4)).
11. ☐ A copy of the International Preliminary Examination Report (PCT/IPEA/409).
12. ☐ A translation of the annexes to the International Preliminary Examination Report under PCT Article 36 (35 U.S.C. 371 (c)(5)).

Items 13 to 18 below concern document(s) or information included:

13. ☒ An Information Disclosure Statement under 37 CFR 1.97 and 1.98.
14. ☐ An assignment document for recording. A separate cover sheet in compliance with 37 CFR 3.28 and 3.31 is included.
15. ☒ A **FIRST** preliminary amendment.
A **SECOND** or **SUBSEQUENT** preliminary amendment.
16. ☐ A substitute specification.
17. ☐ A change of power of attorney and/or address letter.
18. ☒ Certificate of Mailing by Express Mail
19. ☐ Other items or information:

EF 215953247 US

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20. The following fees are submitted:

BASIC NATIONAL FEE (37 CFR 1.492 (a) (1) - (5)) :

- | | |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------|
| <input type="checkbox"/> Search Report has been prepared by the EPO or JPO | \$930.00 |
| <input type="checkbox"/> International preliminary examination fee paid to USPTO (37 CFR 1.482) | \$720.00 |
| <input type="checkbox"/> No international preliminary examination fee paid to USPTO (37 CFR 1.482) but international search fee paid to USPTO (37 CFR 1.445(a)(2)) | \$790.00 |
| <input checked="" type="checkbox"/> Neither international preliminary examination fee (37 CFR 1.482) nor international search fee (37 CFR 1.445(a)(2)) paid to USPTO | \$1,070.00 |
| <input type="checkbox"/> International preliminary examination fee paid to USPTO (37 CFR 1.482) and all claims satisfied provisions of PCT Article 33(2)-(4) | \$98.00 |

ENTER APPROPRIATE BASIC FEE AMOUNT =**\$1,000.00**
 Surcharge of **\$130.00** for furnishing the oath or declaration later than ☐ 20 ☐ 30 months from the earliest claimed priority date (37 CFR 1.492 (e)).
\$0.00

CLAIMS	NUMBER FILED	NUMBER EXTRA	RATE		
Total claims	6 - 20 =	0	x \$18.00	\$0.00	
Independent claims	1 - 3 =	0	x \$80.00	\$0.00	
Multiple Dependent Claims (check if applicable). <input type="checkbox"/>				\$0.00	

TOTAL OF ABOVE CALCULATIONS =**\$1,000.00**
 Reduction of 1/2 for filing by small entity, if applicable. Verified Small Entity Statement must also be filed (Note 37 CFR 1.9, 1.27, 1.28) (check if applicable). ☐
\$0.00**SUBTOTAL =****\$1,000.00**
 Processing fee of **\$130.00** for furnishing the English translation later than ☐ 20 ☐ 30 months from the earliest claimed priority date (37 CFR 1.492 (f)).
\$0.00**TOTAL NATIONAL FEE =****\$1,000.00**
 Fee for recording the enclosed assignment (37 CFR 1.21(h)). The assignment must be accompanied by an appropriate cover sheet (37 CFR 3.28, 3.31) (check if applicable). ☐
\$0.00**TOTAL FEES ENCLOSED =****\$1,000.00**

Amount to be refunded	\$
charged	\$

- ☐ A check in the amount of _____ to cover the above fees is enclosed.
- ☒ Please charge my Deposit Account No. **19-4675** in the amount of **\$1,000.00** to cover the above fees.
A duplicate copy of this sheet is enclosed.
- ☒ The Commissioner is hereby authorized to charge any fees which may be required, or credit any overpayment to Deposit Account No. **19-4675** A duplicate copy of this sheet is enclosed.

NOTE: Where an appropriate time limit under 37 CFR 1.494 or 1.495 has not been met, a petition to revive (37 CFR 1.137(a) or (b)) must be filed and granted to restore the application to pending status.

SEND ALL CORRESPONDENCE TO:

STRIKER, STRIKER & STENBY
103 EAST NECK ROAD
HUNTINGTON, NEW YORK 11743

SIGNATURE

MICHAEL J. STRIKER

NAME

27233

REGISTRATION NUMBER

APRIL 2, 2001

DATE



CERTIFICATE OF ACCURACY

State of New York

} ss.

County of Erie

TRANSLATION FROM German

On this day, I S. Edmund Berger state:

that I am a professional translator of the German and English languages,
doing business as *Chemical Translations*, 298 Grayton Road, Tonawanda, NY 14150;


that I am thoroughly familiar with these languages and have carefully made and/or verified the
attached translation from the original document

USE OF TESTOSTERONE ESTERS AND/OR TESTOSTERONE FOR PRODUCING BUCCALLY
APPLICABLE BIO-ADHESIVE SYSTEMS WITH TIME-RELEASED ACTIVE INGREDIENTS

as submitted to me in the

German language;

and that the said translation is a true, complete and correct English version of such original
to the best of my knowledge and belief.


April 24, 2001



**Use of Testosterone Esters and/or Testosterone
for Producing Buccally Applicable Bio-Adhesive
Systems with Time-Released Active Ingredients**

**Translated from the German for
STRIKER, STRIKER & STENBY**